UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,421	11/18/2005	Breda M Cullen	JJM5002USPCT	4759

27777 7590 04/30/2008

PHILIP S. JOHNSON
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER	
LEWIS, KIM M	

ART UNIT	PAPER NUMBER
3772	

MAIL DATE	DELIVERY MODE
04/30/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/527,421	CULLEN ET AL.	
	Examiner	Art Unit	
	Kim M. Lewis	3772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5-11,13 and 16-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5-11 and 16-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/27/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Detailed Action*.

DETAILED ACTION

This application has been transferred to Primary Examiner, Kim M. Lewis.

Information Disclosure Statement

1. The information disclosure statement filed 8/2/07 has been received and made of record. Note the acknowledged form PTO-1449 or substitute therefor enclosed herewith.

Response to Amendment

2. The amendment filed on 12/12/07 has been received and made of record. As requested, the specification and claims 1, 5, 9 and 13 have been amended. Claims 2-4, 12, 14 and 15 have been cancelled. Claims 16-18 have been newly added.

3. Claims 1, 5-11 and 16-18 are pending in the instant application.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1, 6, 8 and 10 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,409,881 ("Jaschinski").

As regards claims 1 and 10, Jaschinski discloses metal-crosslinkable oxidized cellulose containing fibrous materials and products made therefrom that anticipate applicant's presently claimed invention. More specifically, Jaschinkski discloses wound dressing (bandage) material comprising a complex of an oxidized cellulose with silver, wherein the material comprises from about 0.1wt.% to about 3wt.% of silver (abstract and col. 24, lines 37-51).

Re. claim 6, note the abstract which discloses a nonwoven products constructed from crosslinked cellulose containing fiber material and the disclosure of sheets at col. 1, lines 17-34.

Re. claim 8, note col. 24, lines 45-48, wherein applicants claimed ranges fails within the claimed ranges of 0.1 wt. % to 25 wt. of Jaschinski.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jaschinski in view of U.S. Patent No. 3,032,182 ("Bechtold").

9. Re. claim 11, Jaschinski fails to teach the wound dressing (bandage) is sterile ad packaged in a microorganism-impermeable container. However, Bechtold discloses sterile packaging for use with dressing and various other medical products in order to provide sterilized medical products in a container (package) that prevents the growth of mold or bacteria (col. 3, lines 35-50).

10. In view of Bechtold, it would have been obvious to one having ordinary skill in the art to provide the wound dressing (bandage) of Jaschinski in a package for sterilizing the dressing (bandage) and preventing the growth of bacteria and mold.

11. Claims 5 and13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jaschinski.

12. As regards claim 5, Jaschinski does not disclose the amount of silver in the products is from about 1 to about 50% by weight. At col. 24, lines 45-46, Jaschinski discloses the antimicrobial agent is in an amount of 0.1 to 25.0 wt. %. It has been held that, where the claimed ranges overlap or lie inside ranges disclosed by the prior art, a prima facie case of obviousness exits. *In re Werthein*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F. 2d 1575, 16 USPQ2d 1934 (Fed. Circ. 1990).

13. As regards claim 13, Jaschinski fails to explicitly teach a method for treating various ulcers comprising the step of "applying a wound dressing material directly to the surface of the wound, wherein the wound dressing material comprises a complex of oxidized cellulose with silver wherein the material comprises from abut 0.1% wt% to about 3 wt. % of silver". Applicant should note that it has been held that where the preambular language is part of the definition of the invention, it provides a limitation. Diversitech Corp. v. Century Steps Inc., 850 F. 2d 675, 7 USSPQ2d 1315 (Fed. Cir. 1988). Where, however, the preambular language states a purpose or intended use for the invention, it is not a limitation, but merely an indication of a possible use or the environment in which the invention operates. *Loctite Corp. v. Ultraseal Ltd.*, 781 F. 2d 861, 228 USPQ 90 (Fed. Cir. 1985). In the instant case, the preamble is not a limitation. Thus, while Jaschinski does not disclose that the products are for treating an ulcer, a type of wound, one having ordinary skill in the art would have found it *prima facie* obvious to apply the wound dressing (bandage) to an ulcer in order to prevent the growth of bacteria due to the antibacterial treatment of the bandage and to also protect and cover the wound.

14. With respect to claim 7, Jaschinski fails to disclose the wound dressing (bandage) material comprises from about 0.1 wt % to about 10 wt. % of the complex. However, it has been held that the optimization of proportions in a prior art device is a design consideration within the skill of the art. *In re Reese*, 290 F.2d 839, 129 USPQ 402 (CCPA 1961). Thus, it would have been obvious to one having ordinary skill in the

art to optimize the wound dressing (bandage) complex in order to achieve the desired results.

15. Claims 1, 9 and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over GB 2,314,842 ("Watt et al.") in view of Jaschinski.

16. As regards claims 1, 9 and 16-18, Watt et al. substantially disclose applicant's claimed invention. More specifically, Watt discloses materials such as freeze-dried sponges that can be used as a wound dressing comprising a protein such as collagen complexed with oxidized regenerated cellulose (ORC), wherein the weight ratio of protein collagen and ORC is from 1:99.99 to 99.99:1, which fails within the range of applicant's claimed range (see abstract, page 3, para. 2, and example 1).

Watt et al. fail to disclose that the complex comprises silver from about 0.1 wt. % to above 3 wt. %. Jaschinski, however, teaches that it is known to treat oxidized cellulose with a silver based antibacterial agent in an amount of 0.1 wt. % to 25 wt. % in order to confer antibacterial properties to medical products for the inherent purpose of preventing bacterial growth.

In view of Jaschinski, it would have been obvious to one having ordinary skill in the art at the time the invention was made to treat the wound dressing material of Watt et al. with a silver based antibacterial agent in order to prevent bacterial growth.

Conclusion

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kim M. Lewis whose telephone number is (571) 272-4796. The examiner can normally be reached on Wednesday to Friday, from 5:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco, can be reached on (571) 272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kim M. Lewis/
Primary Examiner
Art Unit 3772

kml
April 24, 2008